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The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS[®]) System held its 12th annual scientific meeting in Washington, DC, bringing together industry, academia, and regulatory experts from around the world to discuss the latest trends in prescription and illicit drug abuse, misuse, and diversion. This year we focused on the ***Evolution of the Opioid Overdose Epidemic***.

Additionally, the RADARS System held its fifth annual international pre-symposium focused on the global experience with prescription drug misuse. Data from multiple countries was presented as we discussed the ***International Landscape of Prescription Medication Misuse***.

International Pre-Symposium
International Landscape of
Prescription Medication Misuse

12th Annual Scientific Meeting
Evolution of the Opioid Overdose
Epidemic

RADARS[®] SYSTEM 12TH ANNUAL SCIENTIFIC MEETING



Washington, DC May 9-10, 2018

RADARS® System 12th Annual Scientific Meeting and International Pre-Symposium

Speakers

- John J. Burke
- Earl L. “Buddy” Carter
- Dan Ciccarone, MD, PhD
- Richard C. Dart, MD, PhD
- Nabarun Dasgupta, MPH, PhD
- Tara Gomes, PhD
- J. Aaron Graham
- Janetta L. Iwanicki, MD
- John Schwarz, PhD
- Tamra E. Meyer, PhD, MPH
- David Wood, MD, FRCP, FACMT, FBPhS, FEAPCCT
- Jon E. Zibbell, PhD

Download the full agenda [HERE](#)



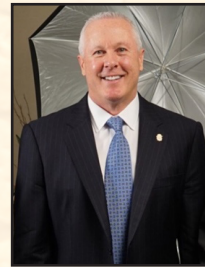
Burke

The Growing Nexus Between NARCOS and Counterfeit Medicines

[Full Presentation Here](#)

Summary:

- Illegal prescription medicines are being sold on the Internet
- While some do not contain active ingredients, many contain fentanyl, which is 25 to 40 times more powerful than heroin
- Some contain carfentanyl, which is 1,000 times more toxic than morphine
- Fentanyl from China is driving the counterfeit pill manufacture
- Stimulant abuse is skyrocketing in 2018



Graham

Welcome and RADARS System 2017 Data Updates

[Full Presentation Here](#)

Effectiveness of ADFs in the Real World

[Full Presentation Here](#)



Ciccarone

Understanding Changes in the US ‘Heroin’ Market: Notes from the Field

[Full Presentation Here](#)

Summary: Heroin in Transition

- The novel entry of Colombian-sourced heroin increased HOD rates; 1993-1999
- New increases in HOD:
 - Regional!
 - New form of Mexican-sourced heroin
 - (+) Fentanyl adulteration
 - Wider distribution models
 - Young users



Dart

Conclusions:

- Opioid prescribing has been declining since 2010
- Deaths from prescription opioids are decreasing substantially
- Abuse of prescription stimulants and other non-opioid drugs may be increasing
- Non-oral routes of abuse surprisingly high for prescription stimulants
- Abuse of other drugs is on the rise
- Illicit fentanyl is our biggest challenge

A Causal Approach to Understanding Abuse in the Community



Dasgupta

Conclusions:

- Current methods are insufficient, but T-in-T addresses many known limitations
- Initial results are consistent with our understanding of opioid dispensing and abuse, but we benefit from challenging our assumptions
- Dispensing tiers are a stronger threat to validity than interventions
- Methods will continue to be developed



Schwarz

Understanding the Evolution of the Opioid Epidemic in Canada, and the Risks of Poly-Substance Use

[Full Presentation Here](#)

Considerations for the Future:

- Ongoing Monitoring of policies/programs
 - Delisting of high strength opioid formulations
 - Canadian guidelines
 - Prescriber 'abandonment'
- Harm reduction as a means of reducing mortality risk with emerging illicit fentanyl analogues
- Engage in dialogue to understand needs/priorities of people with lived experience



Gomes

Welcome and The Global Mosaic: Is Prescription Drug Misuse Really Different Among Countries?

[Full Presentation Here](#)

Conclusions:

- Each component of the global mosaic provides complementary data
- Codeine and tramadol are highly available in multiple countries
- GABA analogues are commonly misused by persons who abuse drugs, most often in setting of polysubstance misuse
- NMURx provides comparable data across countries
- Opioids are most commonly misused medications across all countries
- UK has the highest rate of lifetime opioid misuse, followed by Spain and France
- Spain has the highest rate of lifetime benzodiazepine misuse
- Italy has the highest rate of lifetime GABA analogue misuse



Iwanicki

Thinking Outside the Opioid Box: Non-Opioid Pharmaceutical Abuse

[Full Presentation Here](#)

Summary:

- Nonopioid pharmaceutical drug abuse is becoming more common
- Many likely to be co-abused with opioids
- Synergistic CNS and respiratory depression most common interaction
- Need methods for surveillance and early warning
 - NPDS and NMURx may provide ideas



FDA's Current Approach to the Postmarket Evaluation of Opioid Analgesic Products with Properties Intended to Deter Abuse

[Full Presentation Here](#)

Meyer

Conclusions:

- Addressing the opioid crisis is an agency priority
- "Abuse-deterrent formulations"
 - Are not "abuse proof"
 - Are not designed to prevent addiction
 - Have properties expected to deter abuse through specific routes (e.g., nasal, injection), as demonstrated in premarket assessments
- There are challenges with current postmarketing data used to evaluate abuse-deterrence
- There are both potential positive and negative public health impacts of AD opioid analgesics



The Illicit Injection of Prescription Opioids in Scott County, Indiana: Risks and Rewards

[Full Presentation Here](#)

Zibbel

Conclusions:

- Circumventing anti-crush mechanism (INTAC)
- Circumventing Gelling Associated with ER Excipients
- Rinse shots
- Economics of supply and demand
 - Increase HIV and HCV risk
 - Decreases OD risk
- "House Hopping"
- Filtration: Endocarditis and Pulmonary Embolism
- From Opana to Heroin and Illicitly-made fentanyl
 - Increased overdose risk
- MIPIE associated with other extended-release opioid formulation (e.g., oxycodone ER; hydromorphone ER)
- TTP-like effects reported in Tennessee



Acute Harms of Prescription Drug Misuse: What Can We Learn from the European Drug Emergencies Network (Euro-DEN) Plus Project

[Full Presentation Here](#)

Wood

Conclusions:

- Euro-DEN Plus provides detailed information on the acute harms related to use of prescription medicines
 - Older individuals than recreational drugs and NPS
 - Potentially decreasing presentations related to POM
 - Variability between centres in prescription medicines seen
- Opioids associated with acute harm presentations not the same as opioids of concern in the US
 - Minimal Oxycodone
 - No Oxynorm, Hydromorphone, Hydrocodone
- Drugs causing acute harm correlate with drug sales data
- Provides an additional indicator on prescription medicine misuse to other RADARS mosaic indicators



Dr. Dart greets Hon. Earl "Buddy" Carter

Panel Discussion



International Pre-Symposium speakers panel



Annual Meeting speakers panel



Recent Publications by RADARS® System

RADARS System Published in *Pediatrics*:

Unit-Dose Packaging and Unintentional Buprenorphine-Naloxone Exposures

George Sam Wang, S. Geoffrey Severtson, Gabrielle E. Bau, Richard C. Dart, Jody L. Green

[DOI: 10.1542/peds.2017-4232](https://doi.org/10.1542/peds.2017-4232). [Epub ahead of print](#)

BACKGROUND AND OBJECTIVES:

Buprenorphine accounts for the most opioid-related pediatric hospital admissions when compared with other opioid analgesics. Since 2010, several manufacturers began distributing their buprenorphine products with unit-dose packaging (UDP). Our main objective in this study is to evaluate the impact of UDP on unintentional pediatric buprenorphine-naloxone poison center exposures.

METHODS:

This is an observational surveillance study in which the Researched Abuse, Diversion, and Addiction-Related Surveillance System Poison Center Program is used. The main outcome was cases of unintentional ingestions involving children <6 years old and buprenorphine-naloxone (combination) products. The study was split into 3 periods: pre-UDP (first quarter 2008 through fourth quarter 2010), transition to UDP (first quarter 2011 through fourth quarter 2012), and post-UDP (first quarter 2013 through fourth quarter 2016).

RESULTS:

Overall, there were 6217 exposures to combination products. In the pre-UDP period, there were 20.57 pediatric unintentional exposures per 100 000 prescriptions dispensed; in the transition to UDP period, there were 8.77 pediatric unintentional exposures per 100 000 prescriptions dispensed; and in the post-UDP period, there were 4.36 pediatric unintentional exposures per 100 000 prescriptions dispensed. This represents a 78.8% (95% confidence interval: 76.1%-81.3%; $P < .001$) relative decrease from the pre-UDP period.

CONCLUSIONS:

The shift from non-UDP to UDP in over 80% of buprenorphine-naloxone products was associated with a significant decrease in unintentional pediatric exposures reported to poison centers. Packaging controls should be a mainstay in the approach to the prevention of unintentional buprenorphine pediatric exposures as well as exposures to other prescription opioids.

Rocky Mountain Poison and Drug Center Announcement



We are pleased to announce that Elizabeth Nugent MSPH, CCRP, has been appointed as Director of Clinical Research and Pharmacovigilance at Rocky Mountain Poison and Drug Center effective May 15, 2018.

Ms. Nugent is a leader in clinical research integration and innovation. Merging her analytic and data management background with her passion for program development, she has spent the past 12 years leading the clinical trials program for Kaiser Permanente in the Colorado Region where she coordinated the development and implementation of regional clinical research strategy. Her novel approach to research has grown the program to a national leader in clinical trials research including funding from the National Cancer Institute Oncology Research Program for which Kaiser Permanente is among the top 10 enrolling sites. Ms. Nugent has expertise

in phase I-IV clinical trials, device trials, post-marketing and epidemiologic surveillance as well as operational and administrative management of large, complex, multi-site studies funded by federal, foundation and industry partners. Ms. Nugent is a graduate of Colorado State University (B.S. in Zoology) and University of Colorado (Master of Science in Public Health).



RADARS® System Offers Wide Range of Services Both Domestically and Internationally

The RADARS System data have been utilized by manufacturers, regulatory agencies and medical and public health officials to characterize and monitor prescription drug abuse, misuse and diversion.

The data have been presented at several US Food and Drug Administration (FDA) advisory committee meetings and scientific meetings as well as in reports to the FDA, new drug applications, labeling claims, post market requirements, and Risk Evaluation and Mitigation Strategies (REMS) evaluations. Data may also be used for the development of interventions, to assess the impact of interventions and to monitor ever-changing market trends.

The RADARS System is composed of a mosaic of programs which target diverse populations. Data from these RADARS System programs are triangulated to provide a comprehensive picture of prescription drug abuse, misuse and diversion. Triangulation is an approach used in many fields of research and is especially useful in the study of hard to reach or hidden populations, such as prescription drug abusers. No single data source is expected to provide complete and representative information about a given population, but when considered together, multiple data sources strengthen the credibility of findings, reduce the risk of false interpretations, and

See services available
through the RADARS® System

provide a more complete and comprehensive perspective on the behaviors of the covert population.

The RADARS System has helped clients meet pre- and post-market regulatory and business requirements since 2006. These services are customized to meet specific regulatory and business needs and may include but are not limited to the development of studies, formal epidemiological studies including protocol and statistical analysis plan development, quarterly and annual surveillance reports, and ad hoc analyses/reports as requested.

The RADARS System publishes several articles each year in noteworthy peer-reviewed journals, including the New England Journal of Medicine, JAMA Psychiatry, the Journal of Pediatrics, Drug and Alcohol Dependence and the Clinical Journal of Pain. Further, RADARS System data are regularly presented at scientific conferences throughout the world.

